IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter Defendants.	[redacted]

NS'S MEMORANDUM OF LAW IN SUPPORT OF ITS RESPONSE TO SAREPTA AND UWA'S MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 3 REGARDING NO INEQUITABLE CONDUCT AND NO *WALKER PROCESS* FRAUD

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I INTRODUCTION

The Court should deny Sarepta Therapeutics, Inc. and the University of Western Australia's (together, "Sarepta's") motion for summary judgment of no inequitable conduct and no *Walker Process* fraud (D.I. 398) because there is sufficient evidence upon which this Court could find that Sarepta's asserted patents are unenforceable due to inequitable conduct. More specifically, there is sufficient evidence for the Court to find that the inventors [redacted] and with the specific intent to deceive the PTO.

II CONCISE STATEMENT OF FACTS

NS incorporates by reference its concise statement of facts ("SOF") and responses to Sarepta's Statement of Facts ("Responses") filed contemporaneously herewith.

II. ARGUMENT

Inequitable conduct is a fact-driven inquiry, particularly with respect to intent, which often involves determination of a witnesses' credibility. *See St. Clair Intell. Prop. Consultants, Inc. v. Acer, Inc.,* 961 F. Supp. 2d 610 (D. Del. 2013) (denying summary judgment of no inequitable conduct where genuine issues of material fact existed as the inventor's knowledge and credibility). NS has identified sufficient evidence on which this Court could find that [redacted] misrepresented or omitted material information with the specific intent to deceive the PTO under a clear and convincing standard. *Therasense, Inc. v. Becton, Dickinson & Co.,* 649 F.3d 1276, 1287-90 (Fed. Cir. 2011) ("To prevail on a claim of inequitable conduct, the

accused infringer must prove that the patentee acted with the specific intent to deceive the PTO" with clear and convincing evidence). "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence…. [h]owever … the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id.* at 1290 (citation and internal quotes omitted).

A. There is Sufficient Evidence to Find Inequitable Conduct

[redacted]

Table 39 first appears in PCT/AU2005/000943 ("the 2005 PCT"). SOF ¶ 4. The 2005 PCT was filed on June 28, 2005, and is substantively identical to the specifications of U.S. Patent Nos. 9,994,851 ("the '851 patent"), 10,227,590, and 10,266,827 (collectively, the "UWA Patents"). *Id.* ¶ 1-2. The 2005 PCT and UWA Patents provide in Table 1A a list of "2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA," including SEQ ID NO: 195 and others directed at exon 53. Sarepta Ex. 1, '851 patent at Col. 7. Regarding antisense oligonucleotides ("AOs") directed at exon 53, the specification states that the AOs in Table 39 were "tested at a concentration range of 50, 100, 300 and 600 nM" with the exception of one AO that was "not made yet." SOF ¶ 5. Table 39 provides reports on the listed AOs' "ability to induce skipping" and that testing of SEQ ID NO: 195 showed "Very faint skipping to 50 nM." *Id.* ¶ 7. [redacted]

SEQ ID NO: 195, also referred to as H53A(+23+47), is a critical structural feature of the genus of AOs claimed by the UWA Patents. The limitation "wherein the base sequence comprises at least 12 consecutive bases of [SEQ ID NO: 195]" is found in every claim of the

UWA Patents, and distinguishes the claimed genus of AOs from other exon 53 skipping AOs disclosed in the specification. The written description support for the functional limitation "induces exon 53 skipping" present in every claim of the UWA Patents is found entirely in this single entry in Table 39. SOF ¶ 8.

[redacted]

Dr. Dowdy (NS Ex. 2, Rebuttal Report ¶ 449) [redacted]

[redacted]

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1 [redacted] SOF ¶ 18 (SRPT-VYDS-0158291 at 316-318).

[redacted] SOF ¶ 3. [redacted] This may be done by [redacted] NS Ex. 40, Hirshfeld Dep.

118:12-18.

[redacted] SOF ¶¶ 27-28.

A specific intent to deceive the PTO is the single most reasonable inference to be drawn from [redacted] Moreover, Sarepta and UWA are knowingly and deliberately asserting patents [redacted] This constitutes the very type of egregious misconduct on which the doctrine of inequitable conduct was founded. *Therasense,* 649 F.3d at 1290. Acts undertaken after issuance of the patent can form the basis of inequitable conduct. *See id.* at 1285 (discussing *Keystone Driller Co. v. General Excavator Co.,* 290 U.S. 240, 243 (1933), in which actions taken by the patentee after issuance was the basis of dismissal).

The Federal Circuit has rejected the premise that "in order to invalidate the patent, the inequitable conduct must have occurred in patent prosecution." *Regeneron Pharms., Inc. v. Merus N.V.,* 864 F.3d 1343, 1364 (Fed. Cir. 2017) (affirming adverse inference of specific intent to deceive the PTO based on post-prosecution misconduct that obfuscated prosecution misconduct). Thus, NS has adduced evidence showing that [redacted] acted and are continuing to act with the specific intent to deceive the PTO and this Court. Sarepta's Motion for Summary Judgment No. 3 should be denied on this basis alone.

B. Disputed Factual Issues Preclude Summary Judgment

To the extent Sarepta and UWA dispute the [redacted] those are issues of fact that preclude summary judgment on NS's inequitable conduct defense and *Walker Process* fraud

claim. Other disputed factual issues also preclude summary judgment. These include: when Wilton or Fletcher [redacted]; [redacted] whether it is reasonable to believe the examiner reviewed the references disclosed in the same Information Disclosure Statement as Harding 2007, which totaled tens of thousands of pages, in 9 business days. *See* Responses ¶¶ 3.6, 3.7, 3.13-3.16.

1. *When did Wilton and Fletcher* [redacted]

The timing of Wilton and Fletcher's [redacted] is probative of their intent [redacted] Sarepta Ex. 1, '851 patent, Table 1A, Col. 64:34-35, Table 39. [redacted] SOF ¶ 19 (Adams Dep. 37:14-24, 38:17-20; SRPT-VYDS-0163133 at 231, 233 and 261, 284). It is reasonable to infer [redacted] For example, [redacted] NS Ex. 46, Adams Dep. at 33:20-34:20. As Dr. Wilton testified, [redacted] NS Ex. 38, Wilton Dep. 145:15-146:3. [redacted]

[redacted]

2. *Does Harding 2007 refute the purported "hot spot"?*

Harding et al., Mol. Ther. 15(1):157-166 (2007) ("Harding 2007") is an article by Wilton and Fletcher published in January 2007. SOF ¶ 20. [redacted] NS Ex. 38, Wilton Dep. 110:5-8. The AOs studied in Harding 2007 include SEQ ID NO:195. SOF ¶ 22. Wilton and Fletcher testified [redacted] NS Ex. 38, Wilton Dep 22:1-22 [redacted], 23:22-24:20 ([redacted]), 108:15-19 [redacted]); NS Ex. 39, Fletcher Dep. 114:10-19 [redacted]); 125:8-11 ([redacted]), 201:22-24 ([redacted]). Thus, the work reported in Harding 2007 is contemporaneous or near-contemporaneous with the 2005 PCT even though it was published after the filing date.

Sarepta argues that in the 2005 PCT, Wilton and Fletcher "identified a discrete region within human exon 53 that is amenable for exon skipping" of +23 to +69, thereby overcoming the general unpredictability in the art. *See, e.g.*, NS Ex. 2, Dowdy Rebuttal ¶¶ 31, 131 and n.47 at pp. 248-249. This "hot spot" was identified via four ASOs disclosed in Table 39, including SEQ ID NO: 195, that "collectively target nucleotides +23 to +69 of human exon 53 and induced exon skipping." NS Ex. 2, Dowdy Rebuttal ¶ 67. [redacted]

However, in Harding 2007, Wilton and Fletcher identify the relevant "amenable site[] to redirect dystrophin splicing" as "***39***-69 bases within the 212 base long exon 53." SOF ¶ 23

(emphasis added); *see also* NS Ex. 5, Hastings Opening ¶ 67. Dr. Wilton testified that [redacted]." NS Ex. 38, Wilton Dep. 111:4-13. [redacted]

There are disputed issues of material fact as to whether the statement in Harding 2007 refutes Wilton and Fletcher's current claim that they (i) ever identified an amenable region within exon 53 that was +23+69; and (ii) invented an entire genus of AOs falling within that amenable region defined by the structural feature of having at least 12 consecutive bases of SEQ ID NO: 195. As to the former, [redacted] *See* NS Ex. 5, Hastings Opening ¶¶ 67-70. As to the latter, [redacted] Wilton testified that [redacted] NS Ex. 38, Wilton Dep 228:1-229:17. Fletcher testified [redacted] NS Ex. 39, Fletcher Dep. 14:3-8, 40:25-41:2. [redacted] NS Ex. 39, Fletcher Dep. 162:18-24.

Resolution of these disputed facts is material to whether [redacted] The Court must assess the credibility of Wilton and Fletcher's testimony that [redacted] at

which time point, how that recognition was disclosed to the public, and whether they discovered a genus of exon 53 skipping AOs having common structural features. "Neither an inventor nor his counsel may graft claims onto an earlier specification if those claims do not reflect what the inventor actually invented at the time of the earlier application." *Leviton Mfg. Co. v. Universal Sec. Instruments, Inc.,* 606 F.3d 1353, 1360 (Fed. Cir. 2010) (holding that representations regarding inventorship can be material).

If found not credible, then [redacted] is evidence from which the Court could conclude the single most reasonable inference is their specific intent to deceive the PTO. *See Therasense,* 649 F.3d at 1287. Unlike *Vita-Mix,* [redacted] *Cf.* D.I. 409 at 22 (discussing *Vita-Mix Corp. v. Basic Holding, Inc.,* 581 F.3d 1317, 1332 (Fed. Cir. 2009)). These necessary determinations preclude summary judgment.

3. *Was the submission of Harding 2007 done with the specific intent to obscure its significance?*

While true that Harding 2007 was disclosed to the PTO during prosecution of the UWA patents, it is undisputed that it was submitted in Information Disclosure Statements ("IDS") disclosing well over a thousand references each. Response ¶¶ 3.6, 3.13, 3.15. NS does not dispute that the examiner purported to review each and every one of the thousand-plus references. Response ¶¶ 3.7, 3.14, 3.16. However, it is highly improbable that the examiner actually reviewed each and every word of every reference disclosed. For example, during prosecution of the '851 patent, the examiner purported to have reviewed the eleven hundred-plus references within ***ten days*** of the submission of the IDS in question. Response ¶ 3.7. Sarepta's PTO expert and former Commissioner for Patents Andrew Hirshfeld testified [redacted]

[redacted] NS Ex. 40, Hirshfeld Dep. 73:18-22. Harding 2007 post-dates the claimed priority date of the UWA Patents, and [redacted] NS Ex. 40, Hirshfeld Dep. 74:14-75:3. Thus, there is a question of fact: was the inclusion of Harding 2007 in a lengthy IDS done with the specific intent by the prosecuting attorney in order to obscure its significance.

4. *Did the prosecuting attorney have an obligation under PTO rules to investigate the basis of* [redacted]*?*

There is also a dispute whether, under the circumstances, prosecuting attorney Amy Mandragouras was obligated to re-investigate inventorship in view of Harding 2007, and investigate the provenance of the data [redacted]. Sarepta Ex. 24, Kamholz Opening ¶¶ 75-76; Sarepta Ex. 26, Kamholz Reply ¶¶ 27-28.

C. Dr. Kamholz has not offered opinions on intent

Sarepta's motion for summary judgment leads with a straw man argument: that NS's PTO procedure expert Scott Kamholz is offering opinions on intent. D.I. 409 at 14, 17. Dr. Kamholz's deposition testimony makes clear that he is not doing so, as Sarepta's brief elsewhere concedes. *Id.* at 19 ("Dr. Kamholz expressly testified that he was ***not*** opining that [redacted], 20-21 (same). Sarepta cannot argue that expert testimony on intent is improper and simultaneously rely on the absence of testimony from Dr. Kamholz regarding the intent of the inventors or the prosecuting attorney as a basis on which to find summary judgment of no inequitable conduct. Regardless, the Court does not need Dr. Kamholz to opine on intent to deceive in view of the evidence of that intent discussed herein.

III. CONCLUSION

NS does not dispute that its *Walker Process* fraud antitrust claim rises and falls with its inequitable conduct claim. *See, e.g.*, *TransWeb, LLC v. 3M Innovative Props. Co.,* 812 F.3d 1295, 1307 (Fed. Cir. 2016). Thus, because NS's inequitable conduct claim survives summary judgment, its antitrust counterclaim should survive as well. For the foregoing reasons, the Court should deny Sarepta's Motion for Summary Judgment No. 3 in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

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